

Amendment and Response

Applicant: Timothy R. Ryan et al.

Serial No.: 09/982,299

Filed: October 16, 2001

Docket No.: M190.137.101

Title: ANNULOPLASTY BAND AND METHOD

IN THE CLAIMS

Please cancel claims 30 and 33.

Please add claims 46 and 47.

Please amend claims 1, 44, and 45 as follows:

1.(Currently Amended) An annuloplasty band for repair of an atrio-ventricular valve forming a valve annulus, the band comprising:

a sheath ~~having a perimeter length~~; and

a generally arcuate stiffening element entirely disposed within the sheath, the stiffening element extending from a first end to a second end, wherein each of the first and second ends includes an eyelet adapted to receive a suture for securing the annuloplasty band to the valve annulus;

~~wherein an arc length of the stiffening element is not less than one half the perimeter length of the sheath~~ upon assembly, a maximum transverse width of the sheath at the first and second end eyelets is greater than a maximum transverse width of a remainder of the sheath.

2.(Previously Presented) The annuloplasty band of claim 1, wherein the valve is a mitral valve having an antero-lateral trigone, a posterior leaflet, and a postero-medial trigone;

wherein the arcuate shape of the band generally conforms to an expected natural shape of the valve annulus; and

further wherein the eyelets are adapted to secure the annuloplasty band to the antero-lateral trigone and the postero-medial trigone, respectively, via sutures.

3.(Previously Presented) The annuloplasty band of claim 1, wherein the valve is a tricuspid valve having an anterior leaflet, a posterior leaflet and a septal leaflet, each of the leaflets defined by a base relative to the valve annulus;

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wherein the arcuate shape of the band generally conforms to an expected natural shape of the valve annulus; and

further wherein the eyelets are adapted to secure the annuloplasty band to the base of the septal leaflet and the base of the anterior leaflet, respectively, via sutures.

4.(Original) The annuloplasty band of claim 1, wherein the stiffening element includes a wire having opposite ends bent back onto itself to form the eyelets.

5.(Original) The annuloplasty band of claim 4, wherein the wire is overmolded with an elastomeric material.

6.(Original) The annuloplasty band of claim 5, wherein the elastomeric material includes a material selected from the group consisting of biocompatible thermal plastic elastomer and silicone.

7.(Original) The annuloplasty band of claim 4, wherein the wire is configured to define a compound curve including an intermediate portion having a first radius of curvature and opposite end portions each having a second radius of curvature, wherein the first radius of curvature is greater than the second radius of curvature.

8.(Original) The annuloplasty band of claim 7, wherein each of the end portions includes:
a transition segment extending outwardly from the intermediate portion, the transition segment having the second radius of curvature;
an end segment extending from the transition segment, the end segment having a third radius of curvature;
wherein the second radius of curvature is greater than the third radius of curvature.

9.(Original) The annuloplasty band of claim 1, wherein the stiffening element includes a molded polymeric element.

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10.(Previously Presented) An annuloplasty band for repair of an atrio-ventricular valve forming a valve annulus, the band comprising:

a sheath; and

a generally arcuate stiffening element entirely disposed within the sheath, the stiffening element extending from a first end to a second end, wherein each of the first and second ends includes an eyelet adapted to receive a suture for securing the annuloplasty band to the valve annulus;

wherein the sheath is discretely marked at a first location corresponding to a position of the first end eyelet and at a second location corresponding to a position of the second end eyelet.

11.(Original) The annuloplasty band of claim 10, wherein the sheath is marked to indicate eyelet placement by a suture having a color different from a color of the sheath.

12.(Original) The annuloplasty band of claim 1, wherein the stiffening element is radio-opaque.

13.(Original) The annuloplasty band of claim 1, wherein the sheath is formed of a fabric material.

14.(Original) The annuloplasty band of claim 1, wherein the sheath is formed of biological tissue.

15.(Original) The annuloplasty band of claim 1, wherein the band has a thickness no greater than approximately 3 mm.

16.(Previously Presented) The annuloplasty band of claim 1, wherein the stiffening element is configured to independently maintain a generally arcuate shape in an X-Y plane and a generally saddle-shape in a Z-plane.

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17. – 29.(Cancelled)

30.(Cancelled)

31. – 32.(Cancelled)

33.(Cancelled)

34. – 36.(Cancelled)

37.(Previously Presented) An annuloplasty device for repair of an atrio-ventricular valve forming a valve annulus, the device comprising:

a sheath;

a reinforcing member having a first eyelet, the reinforcing member being disposed entirely within the sheath such that the first eyelet is located at a first location relative to a curvature of the sheath; and

a visible marking formed on the sheath at the first location, the visible marking identifying a position of the first eyelet relative to the sheath.

38.(Previously Presented) The annuloplasty device of claim 37, wherein the reinforcing member is generally arcuate in the X-Y plane.

39.(Previously Presented) The annuloplasty device of claim 37, wherein the reinforcing member is saddle-shaped in the Z-plane.

40.(Previously Presented) The annuloplasty device of claim 37, wherein the visible marking comprises a suture having a color different from a color of the sheath.

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41.(Previously Presented) The annuloplasty device of claim 37, wherein the device has a thickness no greater than approximately 3 mm.

42.(Previously Presented) The annuloplasty device of claim 37, wherein the visible marking is configured to indicate an area within the first eyelet.

43.(Previously Presented) The annuloplasty device of claim 37, wherein the reinforcing member includes a second eyelet opposite the first eyelet such that upon final assembly, the second eyelet is located at a second location along a curvature of the sheath, the device further comprising:

a second visible marking formed on the sheath at the second location.

44.(Currently Amended) An annuloplasty band for repair of an atrio-ventricular valve forming a valve annulus, the band comprising:

a sheath; and

a generally arcuate stiffening element entirely disposed within the sheath, the stiffening element extending from a first end to a second end, wherein each of the first and second ends includes an eyelet adapted to receive a suture for securing the annuloplasty band to the valve annulus;

wherein an entirety of a perimeter shape of the sheath is defined by the stiffening element ~~for at least one-half a perimeter length of the sheath.~~

45.(Currently Amended) An annuloplasty band for repair of an atrio-ventricular valve forming a valve annulus, the band comprising:

a sheath; and

a generally arcuate stiffening element entirely disposed within the sheath, the stiffening element including ~~an intermediate~~ a middle section extending from a first end eyelet to a second end eyelet each adapted to receive a suture for securing the annuloplasty band to the valve annulus, wherein a first point is defined at a

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transition of the ~~intermediate~~middle section and the first end eyelet, and a second point is defined at a transition of the ~~intermediate~~middle section and the second end eyelet, and further wherein a linear distance between the first and second points is greater than a linear distance between the first end eyelet and the second end eyelet.

46. (New) The annuloplasty device of claim 37, wherein the visible marking is a cross.

47. (New) An annuloplasty device for repair of an atrio-ventricular valve forming a valve annulus, the device comprising:

a reinforcing member forming opposed, first and second eyelets; and

a sheath entirely encompassing the reinforcing member, the sheath defining closed, first and second ends corresponding with the first and second eyelets, respectively.